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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,955	05/16/2000	WOLFGANG ROHDE	23232.0002	5703

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	17

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,955	ROHDE ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 6, 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed January 6, 2003, paper no. 16, has been entered.

Claims 11 and 24 are cancelled.

Claims 12-19, 21-23 and 25 are newly amended.

Claim 26 is newly added.

Claims 12-23 and 25-26 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Objections

Claim 18 remains objected to because the adjective "fungi" is plural, whereas the noun "cell" modified is singular. It is suggested that the claim be amended to recite "fungal" rather than "fungi" in order to overcome the objection.

Response to Amendment

The amendment filed September 26, 2001 remains objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure, for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that the references to Rohde in the specification are sufficient to demonstrate that Applicants were in possession of the claimed sequence. Applicant also points to *Enzo Biochem. Inc. v. Gen-Probe* in support of their argument that SEQ ID NO:1 was adequately described in the original disclosure (reply pages 6-8).

The Examiner maintains that the reference to Rohde in the specification is not sufficient to overcome the new matter objection as the specification does not indicate that the Rohde publication is to be incorporated by reference. Furthermore, *Enzo Biochem. Inc. v. Gen-Probe* is distinguishable from the instant case. In *Enzo*, the deposit was made by the Applicant and was incorporated by reference in the specification (296 F3d 1316, 1326). In the instant case, the sequence at issue was not deposited by the Applicants, and was not incorporated by reference in the specification. The sequence at issue here was disclosed in a prior art reference that was mentioned in the specification.

Claim Rejections - 35 USC § 112

Claim 16 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "variant", for the reasons of record set forth in the office action mailed July 3, 2002.

Claim 16 also remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of " a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of nucleotides 211-911 of SEQ ID NO:1", for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that amendment of the claim to remove the term "conserved" moots the Examiner's concerns. Applicants also argue that one skilled in the art would readily understand the claim language to mean that the DNA fragment of claim 16 demonstrates promoter activity which is within 20% of the promoter activity of the starting fragment. Applicants further argue that support for the claim can be found throughout the specification, and that the specification discloses specific examples that meet the claim limitations in Tables 2 and 3. Applicant additionally argues that one skilled in the art could identify molecules that fall within the claims (reply page 9).

The Examiner maintains that removal of the term "conserved" does not overcome the rejection. Removal of the term "conserved" does not clarify the metes and bounds of the term "variant". It is still unclear how different from SEQ ID NO:1 the DNA fragment can be to be a "variant". The Examiner also maintains that one skilled in the art would not understand the claim language to mean that the DNA fragment of claim 16 demonstrates promoter activity which is within 20% of the promoter activity of the starting fragment, as the claim does not refer to "promoter activity which is within 20% of the promoter activity of the starting fragment". The Examiner further maintains that because the metes and bounds of the claim are unclear, it cannot be determined whether the examples disclosed within the specification meet the claim limitations, and one skilled in the art could not determine whether a particular molecule would fall within the claims.

Claims 17-20 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that the addition of claim 26 and the amendment of claims 17 and 19 to depend from claim 26 should overcome the rejection (reply page 10).

The Examiner maintains that the addition of claim 26 and the amendment of claims 17 and 19 to depend from claim 26 does not overcome the rejection. First, amended claims 17 and 19 and newly added claim 26 are indefinite for additional reasons set forth below. Second, claims 17 and 19 are still directed to a method of expressing a nucleic acid by transfecting a cell with "one or more DNA fragments". It is still unclear how transfecting a cell with "one or more DNA fragments" would result in the expression of a nucleic acid.

Claims 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 19 recite the limitation "DNA fragments according to Claim 26". There is insufficient antecedent basis for "DNA fragments" in the claim 26.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 26 recites the limitation "The composition of claim 12". There is insufficient antecedent basis for "The composition" in the claim 12.

Claims 12, 13, 17-21 and 23 remain rejected, and claims 25-26 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for CFDV virus fragment of at least nucleotides comprising position 711-991 of SEQ ID NO:1, which has promoter activity, does not reasonably provide enablement for a CFDV virus fragment that has promoter activity that only has the stem-loop structure set forth in nucleotides 962-991 of SEQ ID NO:1, for the reasons of record set forth in the office action mailed July 3, 2002.

Claims 16 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that the amendments to claims 12 and 23 address the Examiner's concerns regarding claims drawn to fragments comprising the stem-loop. Applicants also argue that claim 16, directed to variants, is enabled because variants are described in the specification, particularly in Figure 2 and at page 5. Applicants argue that one skilled in the art would know how to make and use such variants, and that Applicants provide a standard by which variants can be tested. Applicants argue that it would not require undue experimentation for one skilled in the art to make and use the claimed variants, and points to the case of *In re Wands*. Applicants argue

that the instant situation closely parallels the situation in *Wands*. Applicants additionally argue that what is known in the art need not be disclosed in order to enable the claimed invention. Applicants also argue that the use of DNA fragments in transgenic plants is well known in the art and does not require undue experimentation (reply pages 11-16).

Regarding the amendments to claims 12 and 23, amendment of the claims to recite "nucleotides 734 to 785 set forth in SEQ ID NO:1, and nucleotides 941 to 971 of SEQ ID NO:1" rather than "the stem-loop structure" does not overcome the rejection. As discussed in the office action mailed July 3, 2002 at pages 6-7, the claimed promoter only requires the stem-loop structure, and does not identify the other specific region(s) necessary for promoter function. Amendment of the claims to recite the location of the nucleotides corresponding to the stem-loop structure does not provide any additional guidance with respect to the identity and location of other specific region(s) necessary for promoter function.

The Examiner also maintains that the specification is not enabling for any variant of SEQ ID NO:1 or fragment thereof wherein the fragment is a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of nucleotides 211-911 of SEQ ID NO:1. Figure 2 discloses only the stem-loop structure of geminiviruses and CFDV, but does not disclose any particular variant of SEQ ID NO:1, or any fragment of SEQ ID NO:1 that has been modified. Page 5 of the specification merely asserts that the invention relates to CFDV DNA fragments having promoter function in which individual nucleotides or smaller groups of nucleotides have been subject to substitution, deletion, insertion or modification, but page 5 of the specification provides no guidance with respect to which individual nucleotides or smaller groups of nucleotides may be changed, or what type of substitutions, deletions, insertions or

modifications may be made. Furthermore, the rejected claims are not directed to methods of making and testing variants of SEQ ID NO:1 or modified fragments thereof, but to the variants and modified fragments themselves and their use as promoters. In order to enable such DNA sequences, the specification must provide sufficient guidance for one skilled in the art to be able to discriminate between operative and inoperative embodiments on the basis of their structure before they are tested or used. The disclosure of four specific fragments of CFDV that function as promoters does not provide one skilled in the art with sufficient structural information to make this determination without undue experimentation.

The Examiner additionally disagrees that the instant situation closely parallels the situation in *Wands*. The instant situation is distinguishable in important aspects from the facts in *Wands*. In *Wands*, the dispute over enablement centered on the predictability of producing high affinity IgM antiHBsAg antibodies for use in the claimed immunoassay methods. Here enablement centers on the predictability of variant polynucleotide sequences functioning as promoters. As discussed below with respect to the written description rejection, antibodies and promoters are structurally and functionally dissimilar molecules. Because promoters function by interacting with multiple regulatory proteins at multiple protein binding sites, and because the number and location of protein binding sites varies between different promoters, it would require undue experimentation for one skilled in the art to make and use the claimed variant promoter sequences absent guidance from the specification with respect to which nucleotides of SEQ ID NO:1 may be changed without eliminating its promoter function. It is this type of guidance, which is not known in the art, that Applicants need to disclose in order to enable the full scope of the claimed invention.

Regarding the use of DNA fragments in transgenic plants, the Examiner does not dispute that techniques for plant transformation are well known in the art and well developed. The Examiner maintains, however, that Applicants have not provided sufficient guidance for one skilled in the art to determine, without undue experimentation, how to use plants transformed with Applicants' specifically claimed DNA fragments. In the absence of guidance for how to use plants transformed with the claimed DNA fragments, the invention is not enabled.

Claims 16 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that the claimed molecules are fully described because various molecules having the claimed attributes are disclosed, and one skilled in the art would recognize Applicants' possession of them. Applicants also argue that the written description requirement does not absolutely require disclosure of the structure of biological molecules, pointing to the Written Description Guidelines and *Enzo II* in support of their argument. Applicants also argue that the application of the Written Description Guidelines to antibodies is very similar to the technology at issue here (reply pages 17-19).

While Applicants have described four specific fragments of CFDV that exhibit promoter function, Applicants have not described any variant of SEQ ID NO:1 that has promoter function, and Applicants have not described any fragment of SEQ ID NO:1 that has been modified and which does not have 20% more than or 20% less than the promoter activity of nucleotides 211-911 of SEQ ID NO:1. Applicants have not described what nucleotides of SEQ ID NO:1 could be changed without eliminating promoter function, and Applicants have not described what type of modifications can be made to fragments of SEQ ID NO:1 such that the fragments would exhibit the require level of promoter activity.

Regarding Applicants' argument that the written description requirement does not absolutely require disclosure of the structure of biological molecules, Applicants fail to specifically explain why the description of four specific fragments of CFDV that exhibit promoter function is sufficient to support the description the description of a broad genus of promoter sequences that encompasses any variant of SEQ ID NO:1 and every fragment thereof that is a modified promoter which does not have 20% more than or 20% less than the promoter activity of nucleotides 211-911 of SEQ ID NO:1.

The Examiner also disagrees with the argument that the application of the Written Description Guidelines to antibodies is very similar to the technology at issue here. Antibodies and promoters are structurally and functionally dissimilar molecules. Antibodies are multimeric polypeptides that function by binding a specific antigen at an antigen-binding site, the location of which is common to all antibodies. In contrast, promoters are polynucleotides that function by interacting with multiple regulatory proteins at multiple protein binding sites, many of which vary in composition and location between different promoters. Because antibodies and promoters

are structurally and functionally dissimilar molecules, the application of the Written Description Guidelines to antibodies and promoters is different.

Claim Rejections - 35 USC § 102

Claim 16 remains rejected under 35 U.S.C. 102(b) as being anticipated by Rohde for the reasons of record set forth in the office action mailed July 3, 2002.

Applicants' arguments filed January 6, 2003, have been fully considered but they are not persuasive.

Applicants argue that the amendment of claims 16 and 23 to refer to the translation start site for ORF 1 should overcome the rejection (reply page 19).

While claim 23 was amended to recite that the DNA fragment does not comprise the translation start for open reading frame ORF2 as set forth as nucleotides 1215 to 1217 of SEQ ID NO:1, amended claim 16 makes not reference to the translation start site for ORF 1 and thus remains rejected.

Double Patenting

Claims 12-23 and 25 remain rejected, and claim 26 is rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,303,345.

The Examiner acknowledges Applicants' assertion that a Terminal Disclaimer will be submitted when the application is in condition for allowance (reply page 19). Claims 12-23 and 25-26 are pending.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
March 23, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638